

Appl. No. 10/519,855  
Amdt. dated: April 7, 2008  
Reply to Office Action of: January 9, 2008

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**Amendments to the Drawings:**

Please replace sheets 1-3 of the drawings with attached Replacements Sheets 1-5.

### **REMARKS/ARGUMENTS**

This application has been carefully reviewed in light of the Office Action dated January 9, 2008. By way of this amendment, new claims 8-11 have been added, and claims 1-7 have been canceled. Sheets 1-3 of the drawings have been replaced with Replacement Sheets 1-5. The specification has been amended to include missing Table 1 and Table 2 as provided on Incorporated Sheets 1-5.

All Incorporated Sheets claim incorporation to PCT/JP03/08305 and WO 2004/003021 as required by MPEP § 1.57, and an English translated copy of the priority document is provided as United States Patent Publication No. 2006/0292160. Replacement Sheets 2 and 4 also claim incorporation to PCT/JP03/08305 and WO 2004/003021 as required by MPEP § 1.57, and an English translated copy of the priority document is provided as United States Patent Publication No. 2006/0292160.

#### **Failure to comply with 37 C.F.R. § 1.821-1.825**

The specification was objected to under the provisions set forth by 37 C.F.R. § 1.821-1.825 for failing to identify sequences in the specification and/or drawings with a sequence identifier. Replacement Sheets 1-5 and Incorporated Sheets 1-5 have been added to further identify the sequence listings.

#### **Objections to the Specification**

The specification was objected to because Tables 1 and 2 were listed but not provided. Incorporated Sheets 1-5 are provided to address this objection and show missing

**Table 1 and Table 2.**

The disclosure referenced five figures, while only three appeared in the application. Replacement Sheets 2 and 4 are provided to amend the drawings to include the missing figures. The inadvertently omitted portion of the drawings can be found on sheets 3 and sheet 5 of the translated application, United States Patent Publication No. 2006/0292160.

The drawings were also objected to for failing to include a figure designation. Replacement Sheets 1, 3, and 5 are provided in response to the Examiner's rejection that the figures did not include a figure designation.

**Rejections under 35 U.S.C. § 112, Second Paragraph**

Claims 1-7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-6 have been cancelled in light of this rejection.

**Rejections under 35 U.S.C. § 112, First Paragraph**

Claims 4-7 are rejected under 35 U.S.C. § 112, first paragraph for failing to provide an enabling disclosure for the claimed invention. Claims 1, 4, and 5 are rejected for containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 2-5 are rejected because the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1-7 have been cancelled in light of this rejection.

The present invention is directed to a monoclonal antibody falling within the category of human IgM which specifically recognizes HIV-infected cells and induces apoptosis. Using the obtained antibody, it is intended to provide a remedy for patients suffering from HIV-infection, which contains as the active ingredient a human IgM antibody capable of specifically reacting with HIV-infected cells, inducing apoptosis in the infected cells and thus disrupting the cells.

In response to the Examiner's rejections, new claims 8-11 are presented. Claim 8 provides a human IgM monoclonal antibody specifically recognizing HIV-infected cells and including apoptosis of the infected cells, said antibody denominated 2G9 antibody obtainable by a cell strain with an accession No.FERM BP-8378, and comprising sequence a H-chain variable region encoded by the base sequence SEQ ID No.1 and a L-chain variable region encoded by the base sequence SEQ ID No.2. Support for the newly added claims can be found in at least Fig. 1, which shows that the HIV-infected cells are recognized, Fig. 3, which shows that apoptosis is introduced into the HIV-infected cells, the accession number as indicated in the paragraph beginning on page 6, line 3, and SEQ ID Nos. 1 and 2 as indicated in the sequence listing filed with the USPTO on September 14, 2005.

The cell has also been deposited in the International Patent Organism Depository (IPOD) in Japan and is available through accession No. FERM BP-8378. The IPOD complies with the terms of the Budapest treaty, and all restrictions imposed by the

depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent.

The Director is hereby authorized to charge any additional fees or any underpayments which may be required for the above-referenced application to Deposit Account No. 01-0265.

Respectfully submitted,

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File No.: 3348/1

TABLE 1

Base Sequence of  $\mu$ -Chain Variable Region

TGCCCTGGATTCCAAGGCCTATCCACTTGGTGATCAGCACTGAGCACCGAGG  
ATTCACCATGGAACTGGGGCTCCGCTGGGTTTTTCCTTGTTGCTATTTTAGAA  
GGTGTCCAGTGTGAGGTGCAGCTGGTGGAGTCTGGGGGAGGCCTGGTCAAG  
CCTGGGGGGTCCCTGAGACTCTCCTGTGCAGCCTCTGGATTACCTTCAGTA  
CTTATAGCATGAACTGGGTCCGCCAGGCTCCAGGGAAGGGGCTGGAGTGGG  
TCTCATCCATTAGTAGTAGTAGTAGTTACATATACTACGCAGACTCAGTGAA  
GGGCCGATTACCATCTCCAGAGACAACGCCAAGAACTCACTGTATCTGCAA  
ATGAACAGCCTGAGAGCCGAGGACACGGCTGTGTATTACTGTGCGAGAGAT  
CTCCTTATAGCAGTGGCTGGCCACTGGGGCCAGGGAACCCTGGTCACCGTCT  
CCTCA

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Base Sequence of  $\kappa$ -Chain Variable Region

CTCAGTCAGGACACAGCATGGACATGAGGGTCCCTGCTCAGCTCCTGGGACT  
CCTGCTGCTCTGGCTCCCAGATACCAGATGTGACATCCAGATGACCCAGTCT  
CCATCCTCCCTGTCTGCATCTGTAGGAGACAGAGTCACCATCACTTGCCGGG  
CGAGTCAGGGCATTAGCAATTATTTAGCCTGGTATCAGCAGAAACCAGGGAA  
AGTTCCTAAACTCCTGATCTATGCTGCATCCACTTTGCAATCAGGGGTCCCA  
TCTCGGTTCAGCGGCAGTGGATCTGGGACAGATTTCACTCTCACCATCAGCA  
GCCTGCAGCCTGAAGATGTTGCAACTTATTACTGTCAAAAGTATAACAGTGC  
CCCGTACACTTTTGGCCAGGGGACCAAGCTGGAGATCAAA

TABLE 2: Examples of cDNA encoding equivalent amino acids  
in the amino acid sequences of 2G9 antibody

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M	E	L	G	L	R	W	V	F	L	V	A	I	L	E	G	V	Q	C	E
ATA	GAA	TTA	GGT	TTA	CGT	TGA	GTT	TTT	TTA	GTT	GCT	ATT	TTA	GAA	GGT	GCT	CAA	TGT	GAA
ATG	GAG	TTG	GSC	TTG	CGC	TGG	GTC	TTT	TTG	GTC	GCC	ATC	TTG	GAG	GGC	GTC	CAG	TGC	GAG
CTT	GGA	CTT	CGA	GTA	CTT	GTA	GCA	CTT	GTA	GCA	CTT	GTA	GCA	CTT	GTA	GCA	CTT	GTA	GCA
CTC	GGG	CTC	CGC	CTC	GGG	CTC	CGC	CTC	GGG	CTC	CGC	CTC	GGG	CTC	CGC	CTC	GGG	CTC	CGC
CTA	CTA	CTA	CTA	CTA	CTA	CTA	CTA	CTA	CTA	CTA	CTA	CTA	CTA	CTA	CTA	CTA	CTA	CTA	CTA
CTG	CTG	CTG	CTG	CTG	CTG	CTG	CTG	CTG	CTG	CTG	CTG	CTG	CTG	CTG	CTG	CTG	CTG	CTG	CTG

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V	Q	L	V	E	S	G	G	G	L	V	K	R	G	G	S	L	R	L	S
GTT	CAA	TTA	GTT	GAA	TCT	GGT	GGT	GGT	TTA	GTT	AAA	ECG	GGT	TCT	TTA	CGT	TTA	TCT	TCT
GTC	CAG	TTG	GTC	GAG	TGC	GGC	GGC	GGC	TTG	GTC	AAG	CCC	GGC	GGC	TCC	TTG	GGC	TTG	TCC
GTA	CTT	GTA	TCA	GGA	GGA	GGA	GGA	CTT	GTA	CCA	GGA	GGA	TCA	CTT	GGA	CTT	GTA	TCA	TCA
GTC	CTG	CTG	TGC	GGG	GGG	GGG	GGG	CTC	GTC	CCG	GGG	GGG	TCC	CTC	GGG	CTC	GGG	CTC	TCC
CTA	CTA	CTA	AGT	AGT	AGT	AGT	AGT	CTA	CTA	AGT	CTA	AGT	CTA	AGT	CTA	AGT	CTA	AGT	CTA
CTG	CTG	CTG	AGC	AGC	AGC	AGC	AGC	CTG	CTG	AGC	CTG	AGC	CTG	AGC	CTG	AGC	CTG	AGC	CTG

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C A A S G F T P S T Y S M N V R Q A P  
TGT GGT GGT TCT GGT TTT ACT TTT TCT ACT TAT TCT ATA ATT TGA GTT CGT CAA GGT CCT  
TGC GCC GCC TCC GGC TTC ACC TTC ACC TAC ACC ATG AAC TGG GTC CSC CAG GCC CCC  
GCA GCA TCA GGA ACA TCA ACA TCA CTA CGA GCA CGA  
GCG GCG TCG GGG ACQ TCG ACB TCB GTG CCG GCG CCG  
AGT AGT AGT  
AGC AGC AGC

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G K G L E W V S S I S S S S Y I Y Y A  
GGT AAA GGT TTA GAA TGA GTT TCT TCT ATT TCT TCT TCT TCT TAT ATT TAT TAT GCT  
GGC AAG GGC TTG GAG TGG GTC TCC TCC ATC TCC TCC TCC TCC TAC ATC TAC TAC GCC  
GGA GCA CTT CTA TCA TCA CTA TCA TCA TCA TCA GCA  
GGG GGG CTT GTG TCG TCG TCG TCG TCG TCG TCG TCG GCG  
CTA AGT AGT AGT AGT AGT AGT AGT AGT  
CTG AGC AGC AGC AGC AGC AGC AGC AGC

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D	S	Y	R	G	R	F	T	I	S	R	D	N	A	K	N	S	L	Y	L
GAT TGT GTT AAA GGT GGT TTT ACT ATT TCT CGT GAT GAT GGT AAA AAT TCT TTA TAT TTA																			
GAC TCC CTC AAG GGC CGC TTC ACC ATC TCC GGC GAC AAC GGC AAG AAC TCC TTG TAC TTG																			
TCA CTA	CCA CGA	ACA	TCA CCA	GCA	TCA CTT	CTT													
TGG CTG	GGG CGG	AGG	TGG CCG	GGG	TGG CTG	CTC													
AGT			AGT		AGT CTA	CTA													
AGC			AGC		AGC CTG	CTG													

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[illegible]

**121**

[illegible]